I. Objections to the Claims

Claim 10 and the claim numbering stand objected to because of informalities. Applicants wish to extend their gratitude to the Examiner for bringing the informalities to their attention. Claim 10 has been cancelled and applicants recognize that misnumbered claims 27-28 are renumbered as 26-27. Accordingly, it is respectfully requested that the objections be withdrawn.

II. Rejections under 35 USC §112

Claim 6 stands rejected under 35 USC § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 has been cancelled. Accordingly, it is respectfully requested that the rejection be withdrawn.

III. Rejections under 35 USC §102

Claims 1-2, 7, and 10-13 stand rejected under 35 USC § 102(b) as being anticipated by Pless et al. (US 5,131,388). Applicant traverses the rejection of claim 1.

Claim 1 defines a structure for a battery enclosure, within an implantable medical device (IMD) housing assembly, having characteristics critical for the containment of a flat liquid electrolyte battery. The battery enclosure structure manages naturally occurring swelling of the flat liquid electrolyte battery by biasing the swelling away from electronics supported upon a flexible circuit substrate, which also reside in the IMD housing assembly. The battery enclosure structure is not anticipated by Pless et al. (US 5,131,388) since Pless et al. do not define a structure for a battery enclosure necessary for integration of a flat liquid electrolyte battery with electronics supported upon a flexible circuit substrate within an IMD housing assembly. Such a structure, defined herein, includes a cover for the enclosure with a greater rigidity, in terms of thickness or modulus of elasticity, than an opposing shell of the enclosure.

Claims 2, 7, and 10-13 are cancelled without prejudice.

IV. Rejections under 35 USC §103

Claims 3-5 stand rejected under 35 USC § 103(a) as being unpatentable over Pless et al. (US 5,131,388). Claims 3-5 are cancelled without prejudice.

Claims 6, and 14-16 stand rejected under 35 USC § 103(a) as being unpatentable over Pless et al. (US 5,131,388). Applicant traverses the rejection of claim 14. Those elements of claim 1, incorporated into claim 14, in combination with a coined edge of the cover and a butt weld between the coined edge and a substantially straight peripheral wall portion of the first shell provide a novel structure suitable for a battery enclosure. Pless et al. in combination with known art do not render obvious the claimed elements of the structure defined in claim 14 of the present invention.

Claims 6, 15, and 16 are cancelled without prejudice.

Claims 8 and 9 stand rejected under 35 USC § 103(a) as being unpatentable over Pless et al. (US 5,131,388). Claims 8 and 9 are cancelled without prejudice.

Claims 17-27 stand rejected under 35 USC § 103(a) as being unpatentable over Pless et al. (US 5,131,388). Applicant traverses the rejection of claims 17, 20, and 25.

Those elements of claim 1, incorporated into claim 17, in combination with a spanked edge of the first shell and a spank weld joint between the spanked edge and a peripheral edge of the cover provide a novel structure suitable for a battery enclosure. Claim 20 further defines the first shell of the novel structure with a ledge that the peripheral wall engages. Pless et al. in combination with known art do not render obvious the claimed elements of the structure defined in claims 17 and 20 of the present invention.

Those elements of claim 1, incorporated into claim 25, in combination with a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion of the first shell, a substantially straight peripheral wall portion of the cover, and a standing edge weld joint between the substantially straight peripheral wall portion of the cover and either the first or the second substantially straight peripheral wall portion of the first shell provide a

novel structure suitable for a battery enclosure. Pless et al. in combination with known art do not render obvious the claimed elements of the structure defined in claim 25 of the present invention.

Claims 18-19, 21-24, and 26-27 are cancelled without prejudice.

New claims 28 - 49 define inventive elements and no new matter has been added as a result of these claims.

V. Reference to Marked-up Version of Changes

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

VI. Conclusion

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

A supplemental IDS is submitted herein. To the best of Applicant's understanding, prior art references included in the supplemental IDS, alone or in combination with the cited prior art, neither anticipate nor render obvious the claimed invention.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Date: May 13, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

From page 3, line 1 to page 6, line 3:

SUMMARY OF THE INVENTION

The present invention is directed to a selectable deformable housing assembly for an implantable medical device (IMD). An IMD housing according to the present invention includes a first shell and a second shell. The first and second shells include an inner surface and an outer surface, respectively. The outer surfaces of the first and second shells are fabricated from a material compatible with body fluids. The implantable medical device further includes a battery enclosure defined by a cover and all or a portion of the first shell of the IMD housing. The cover of the battery enclosure is disposed between the inner surfaces of the first and second shells and has a greater thickness dimension or higher modulus of elasticity than the first shell. An electrochemical battery cell, such as a flat liquid electrolyte battery, is provided in the battery enclosure. Electronic circuitry, [which may be] supported on a flexible wiring substrate, which is electrically coupled to the electrochemical battery cell and a medical electrical lead, is provided between the inner surface of the second shell and the cover of the battery enclosure. A hermetic seal is provided between the cover of the battery enclosure and the applicable portion of the first shell.

The deformable housing assembly is further defined by a feedthrough assembly, which couples the battery to the electronic circuitry. The feedthrough assembly is disposed within a hermetically sealed aperture of the cover and includes a ferrule and a feedthrough pin that are isolated from one another.

The electrochemical battery cell is further defined to include a lithium anode, a cathode with Li/CSVO/CF_x chemistry and a liquid electrolyte of type 1M $LiBF_y$ in GBL/DME.

The hermetic seal provided between the cover of the battery enclosure and the first shell is preferably a weld joint[, such as a butt weld or a tumble weld joint. The hermetic seal may also be established by a spanked weld joint

between the cover and the first shell.] In one embodiment, the battery enclosure cover includes a coined edge and the hermetic seal is established by a butt weld joint between the coined edge of the cover and a peripheral edge of the first shell.

According to another embodiment of the present invention, a housing assembly for an implantable medical device includes a housing comprising a first shell and a second shell, with the outer surfaces of the first and second shells including a material compatible with body fluids. The first shell includes a spanked edge [substantially straight peripheral wall portion]. A battery enclosure is defined by a cover and at least a portion of the first shell of the IMD housing. The cover of the battery enclosure is situated between the inner surfaces of the first and second shells, has a greater thickness dimension or higher modulus of elasticity than the first shell, and includes a peripheral edge. A hermetic seal, according to this embodiment, is established by a spank weld joint between the peripheral edge of the cover and the spanked edge [substantially straight peripheral wall portion] of the first shell.

The [substantially straight peripheral wall portion of the] first shell may further include[s] a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent to the first portion and offset from the first portion to form a ledge, which the peripheral edge of the cover engages. [The hermetic seal may include a spanked edge defined between the peripheral edge of the cover and the substantially straight peripheral wall portion of the first shell.] The hermetic seal is established by a spank weld joint between the peripheral edge of the cover and the spanked edge [substantially straight peripheral wall portion] of the first shell.

According to yet another embodiment, t[T]he cover may also include a substantially straight peripheral wall portion. [The cover, according to this configuration, is a formed cover.] The hermetic seal is established by a standing edge weld joint between the substantially straight peripheral wall portion of the cover and the substantially straight peripheral wall portion of the first shell. [The weld joint, in this configuration, is a standing edge weld joint.]

The present invention is also directed towards a method for assembling a battery into a housing assembly for an IMD including the following steps: providing a shallow drawn case; providing a battery cover having a greater thickness or higher modulus of elasticity than the case; coupling a cathode to the cover; glassing a feedthrough assembly having a feedthrough tube disposed within a ferrule to electrically isolate the feedthrough tube from the ferrule and to bond the feedthrough tube to the ferrule; hermetically sealing the ferrule of the feedthrough assembly to the cover; coupling a feedthrough pin to an anode current collector; placing an insulator tube around the feedthrough pin; placing the cover over the anode current collector while directing the feedthrough pin through the feedthrough tube; coupling the feedthrough pin to the feedthrough tube; and hermetically sealing the cover to the case.

[In accordance with a further embodiment of the present invention, a housing assembly for an implantable medical device includes a housing comprising a first shell and a second shell, with the outer surfaces of the first and second shells formed from a material compatible with body fluids. The first shell includes a substantially straight peripheral wall portion. A battery enclosure of the implantable medical devise includes a cover and at least a portion of the first shell of the IMD housing. The cover of the battery enclosure is situated between the inner surfaces of the first and second shells and includes a coined edge. A hermetic seal is established by a weld joint between the coined edge of the cover and the substantially straight peripheral wall portion of the first shell. The weld joint may be a butt weld joint or a tumble weld joint.

According to yet another embodiment of the present invention, a housing assembly for an implantable medical device includes a housing having a first shell and a second shell, with the outer surfaces of the first and second shells fabricated using a material compatible with body fluids. The first shell includes a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent the first substantially straight peripheral wall portion. The second substantially straight peripheral wall portion is offset relative to the first substantially straight peripheral wall portion.

A battery enclosure of the IMD housing assembly includes a cover and at least a portion of the first shell of the IMD housing. The cover of the battery enclosure is disposed between the inner surfaces of the first and second shells and includes a peripheral edge. The cover is preferably a stamped cover. A hermetic seal is established by a weld joint between the peripheral edge of the cover and either the first or the second substantially straight peripheral wall portions.

The first substantially straight peripheral wall portion of the first shell includes a ledge, which the peripheral edge of the cover engages. The hermetic seal is established by a weld joint between the peripheral edge of the cover and the second substantially straight peripheral wall portion. The hermetic seal may further include a spanked edge defined between the peripheral edge of the cover and the second substantially straight peripheral wall portion. The weld joint in this configuration is a spanked weld joint.

In accordance with a further embodiment of the present invention, a housing assembly for an implantable medical device includes a housing comprising a first shell and a second shell, with the outer surfaces of the first and second shells formed from a material compatible with body fluids. The first shell, according to this embodiment, includes a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent the first substantially straight peripheral wall portion. The second substantially straight peripheral wall portion is offset relative to the first substantially straight peripheral wall portion.

A battery enclosure of the IMD housing assembly includes a cover and at least a portion of the first shell of the IMD housing. The cover of the battery enclosure is situated between the inner surfaces of the first and second shells and includes a substantially straight peripheral wall portion. The cover is preferably a formed cover. A hermetic seal is established by a weld joint between the substantially straight peripheral wall portion of the cover and either the first or the second substantially straight peripheral wall portions of the first shell. The weld joint may be a standing edge weld joint.]

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

On page 6, lines 19 - 30:

Figures 5A-E are [is an] illustrations of a hermetically-sealed IMD battery housing according to another embodiment of the present invention;

Figures 6A-E illustrate[s] another embodiment of a hermetically-sealed IMD battery housing of the present invention;

Figures 7-9 illustrate various embodiments of weld joints for hermetically sealing an IMD battery housing of the present invention;

Figures 10A-D illustrate[s] various showings of a feedthrough in accordance with one embodiment of the present invention;

Figures 11A-D illustrate[s] another embodiment of a feedthrough according to the present invention;

Figures 12A-D illustrate[s] various views of a complete implantable medical device employing a flat battery in accordance with an embodiment of the present invention;

On page 9, line 13:

Figure 2 illustrates an implantable medical device 21, such as an implantable [pace] pulse generator (IPG), which incorporates an integral battery housing for containing a flat liquid electrolyte battery in accordance with the principles of the present invention. The implantable medical device 21 shown in Fig. 2 includes two major sections, namely, an IMD shield section 18 and an IMD battery section 19. A flexible wiring substrate (not shown in Fig. 2) of the present invention is typically disposed between the IMD shield and battery sections 18, 19.

On page 18, line 27:

The feedthrough pin 58 in the anode is bent and the insulative tube assembly is slid up inside the insulator cylinder 55 and seated against the bottom of the feedthrough cylinder to complete insulation of the feedthrough assembly 30. The feedthrough pin 58 may be later welded to the end of the tube 57 to complete the battery assembly process. The feedthrough [pin 58] assembly 30 is also welded to the cover 22 of the battery housing. The feedthrough pin 58 is inserted into the tube 57 and the connection is made by a weld at the tube 57 and pin 58 joint location. This provides for "line of sight" isolation of the feedthrough pin 58 and the feedthrough ferrule 50 to prevent lithium ball shorting. It also provides an easy method for attaching the anode to the feedthrough assembly 30.

On page 19, lines 4-6:

For example, the alumina insulator 55 bonds to the glass 52 and to the tube [57] 56, thus creating a line of sight insulation between the feedthrough tube [56] 57 and the ferrule 50.

On page 19, line 30:

The feedthrough pin 58 may be constructed from [M]Nb, Ti, Mo, or Ta.

On page 25, delete bolded, bracketed text on lines 5-7:

Figure 22 illustrates another embodiment of an implantable medical device which employs a battery compartment 103 separate from the electronics compartment 105. According to this embodiment, the implantable medical device 101 includes three major pieces 103, 105, 107 which snap together to form the completed implantable medical device 101. The electronics compartment 105 is shown to include various implantable medical device

electronics which are mounted to a wiring board, which may be a rigid or flexible wiring substrate. [**[This embodiment is identified at the pre-1990 G. Grose 3-piece snap together IPG – please provided additional disclosure if possible]]**

On page 37:

ABSTRACT OF THE DISCLOSURE

A body implantable medical device (IMD) includes a first shell and a second shell[. The outer surfaces of the first and second shells] whose outer surfaces are [fabricated from a material compatible with body fluids] biocompatible. The [implantable medical device] IMD further includes a battery enclosure defined by a cover and all or a portion of the first shell of the IMD housing. The cover of the battery enclosure is disposed between the inner surfaces of the first and second shells and has a greater rigidity than the first shell. An electrochemical cell, such as a flat liquid electrolyte battery, is provided in the battery enclosure. Electronic circuitry, [which may be] supported on a flexible wiring substrate, is provided between the inner surface of the second shell and the cover of the battery enclosure. A hermetic seal is provided between the cover of the battery enclosure and all or [the] a portion of the first shell. The hermetic seal is preferably a weld joint, such as a butt [weld or a tumble weld joint], spank or standing edge weld joint. [The hermetic seal may also be established by a spanked weld joint between the cover and all or a portion of the first shell. The battery enclosure cover may include a coined edge and the hermetic seal is established by a weld joint between the coined edge of the cover and a peripheral edge along all or the potion of the first shell.]

In the claims:

Claims 2-13, 15, 16, 18, 19, 21-24, 26, and 27 have been cancelled without prejudice.

Claims 1, 14, 20 and 25 have been amended as follows:

1. (Amended) A selectively deformable housing assembly for an implantable medical device [(IMD)], comprising:

a housing comprising a first shell and a second shell, the first and second shells comprising an inner surface and an outer surface, respectively, the outer surfaces of the first and second shells comprising a material compatible with body fluids;

a battery enclosure comprising a cover and all or a portion of the first shell of the [IMD] housing assembly, the cover of the battery enclosure disposed between the inner surfaces of the first and second shells, wherein said cover has a greater thickness dimension or a higher modulus of elasticity than the first shell and an insulated electrical conductor sealingly coupled therethrough;

an electrochemical battery cell [provided] including an anode member, a cathode pellet and a liquid electrolyte disposed in the battery enclosure;

an operable electronic circuit[ry] electrically coupled to the electrochemical battery cell, electrically coupled to a medical electrical lead, and wherein said operable electronic circuit is mechanically coupled [provided] between the inner surface of the second shell and the cover of the battery enclosure and a majority of the operable electronic circuit is coupled to a deformable, flexible circuit substrate; and

a hermetic seal [provided between the cover of] isolating the battery enclosure [and all or the portion of the first shell].

14. (Amended) A selectively deformable housing assembly for an implantable medical device [(IMD)], comprising:

a housing comprising a first shell and a second shell, the first and second shells comprising an inner surface and an outer surface, respectively, the outer surfaces of the first and second shells comprising a material compatible

with body fluids, the first shell comprising a substantially straight peripheral wall portion;

a battery enclosure comprising a cover and all or [at least] a portion of the first shell of the [IMD] housing assembly, the cover of the battery enclosure disposed between the inner surfaces of the first and second shells [and comprising a coined edge], wherein the cover comprises a coined edge and has a greater thickness dimension or a higher modulus of elasticity than the first shell and an insulated electrical conductor sealingly coupled therethrough;

an electrochemical battery cell [provided] including an anode member, a cathode pellet and a liquid electrolyte disposed in the battery enclosure;

an operable electronic circuit[ry] electrically coupled to the electrochemical battery cell, electrically coupled to a medical electrical lead, and wherein said operable electronic circuit is mechanically coupled [provided] between the inner surface of the second shell and the cover of the battery enclosure and a majority of the operable electronic circuit is coupled to a deformable, flexible circuit substrate; and

a hermetic seal comprising a butt weld joint between the coined edge of the cover and the substantially straight peripheral wall portion of the first shell.

17. (Amended) A selectively deformable housing assembly for an implantable medical device [(IMD)], comprising:

a housing comprising a first shell and a second shell, the first and second shells comprising an inner surface and an outer surface, respectively, the outer surfaces of the first and second shells comprising a material compatible with body fluids, the first shell comprising a [substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent to the first substantially straight peripheral wall portion, the second substantially straight peripheral wall portion being offset relative to the first substantially straight peripheral wall portion] spanked edge;

a battery enclosure comprising a cover and all or [at least] a portion of the first shell of the [IMD] housing assembly, the cover of the battery enclosure disposed between the inner surfaces of the first and second shells [and comprising a peripheral edge], wherein the cover comprises a peripheral edge and has a greater thickness dimension or a higher modulus of elasticity than the first shell and an insulated electrical conductor sealingly coupled therethrough;

an electrochemical battery cell [provided] including an anode member, a cathode pellet and a liquid electrolyte disposed in the battery enclosure;

an operable electronic circuit[ry] electrically coupled to the electrochemical battery cell, electrically coupled to a medical electrical lead, and wherein said operable electronic circuit is mechanically coupled [provided] between the inner surface of the second shell and the cover of the battery enclosure and a majority of the operable electronic circuit is coupled to a deformable, flexible circuit substrate; and

a hermetic seal comprising a spank weld joint between the peripheral edge of the cover and [either the first or the second substantially straight peripheral wall portions] the spanked edge of the first shell.

20. (Amended) The deformable housing assembly of claim 17, wherein the [first substantially straight peripheral wall portion of the first shell comprises] first shell further comprises a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent the first substantially straight peripheral wall portion and being offset relative to the first substantially straight peripheral wall portion, the first substantially peripheral wall portion defining a ledge which the peripheral edge of the cover engages.

25. (Amended) A selectively deformable housing assembly for an implantable medical device, comprising:

a housing comprising a first shell and a second shell, the first and second shells comprising an inner surface and an outer surface, respectively, the outer

surfaces of the first and second shells comprising a material compatible with body fluids, the first shell comprising a first substantially straight peripheral wall portion and a second substantially straight peripheral wall portion adjacent the first substantially straight peripheral wall portion and being offset relative to the first substantially straight peripheral wall portion;

a battery enclosure comprising a cover and all or a portion of the first shell of the [IMD] housing assembly, the cover of the battery enclosure disposed between the inner surfaces of the first and second shells [comprising a substantially straight peripheral wall portion], wherein the cover comprises a substantially straight peripheral wall portion and has a greater thickness dimension or a higher modulus of elasticity than the first shell and an insulated electrical conductor sealingly coupled therethrough;

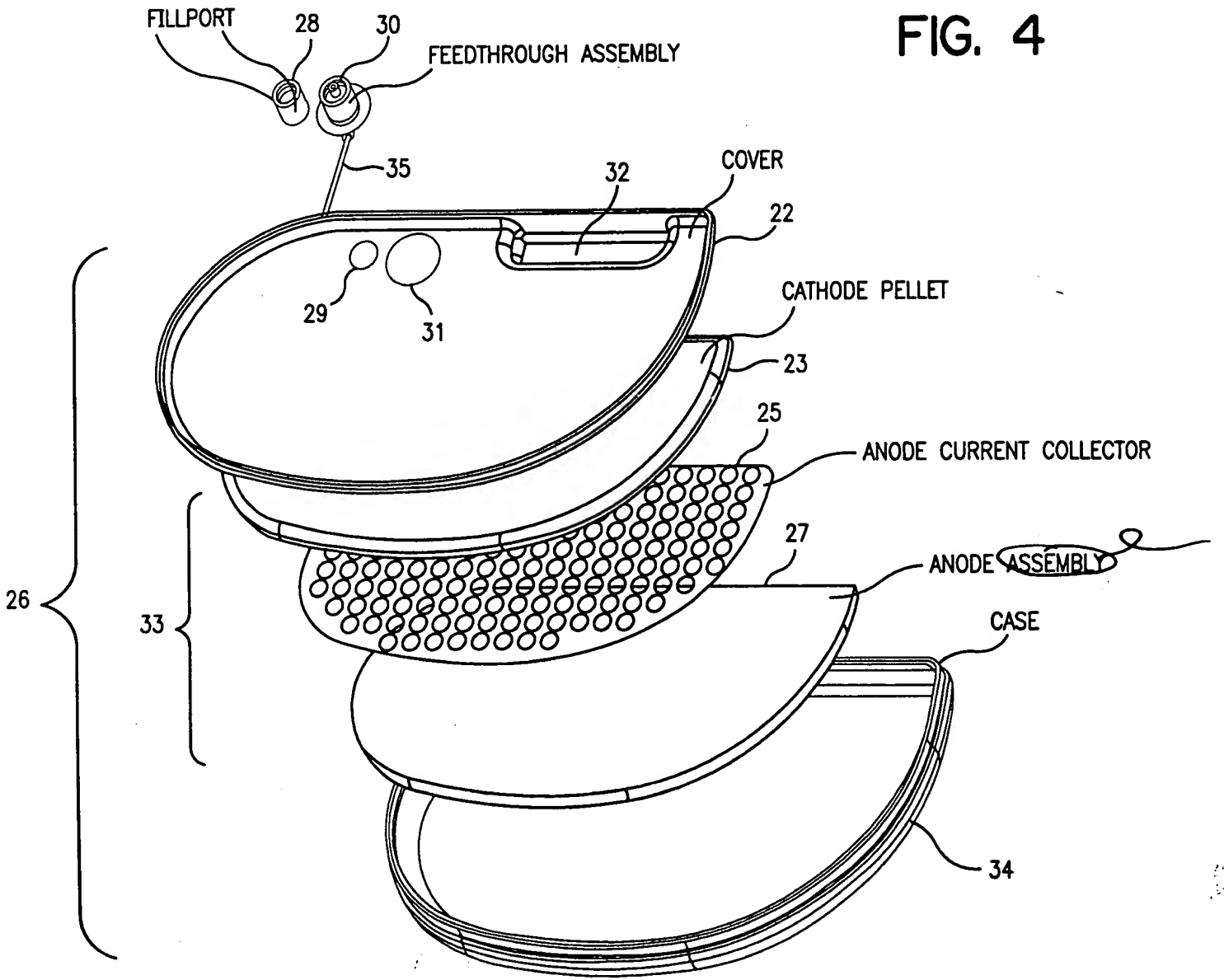
an electrochemical battery cell [provided] including an anode member, a cathode pellet and a liquid electrolyte disposed in the battery enclosure;

an operable electronic circuit[ry] electrically coupled to the electrochemical battery cell, electrically coupled to a medical electrical lead, and wherein said operable electronic circuit is mechanically coupled [provided] between the inner surface of the second shell and the cover of the battery enclosure and a majority of the operable electronic circuit is coupled to a deformable, flexible circuit substrate; and

a hermetic seal comprising a standing edge weld joint between the substantially straight peripheral wall portion of the cover and either the first or the second substantially straight peripheral wall portions of the first shell.

A

FIG. 4


FILLPORT
28
30
FEEDTHROUGH ASSEMBLY
35
32
COVER
22
29
31
CATHODE PELLET
23
25
ANODE CURRENT COLLECTOR
27
ANODE ASSEMBLY
CASE
34
26
33

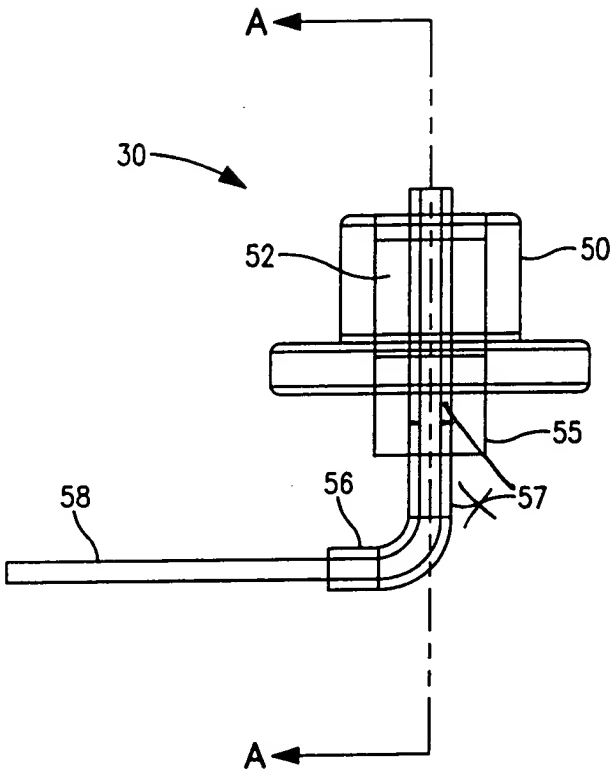


FIG. 11A

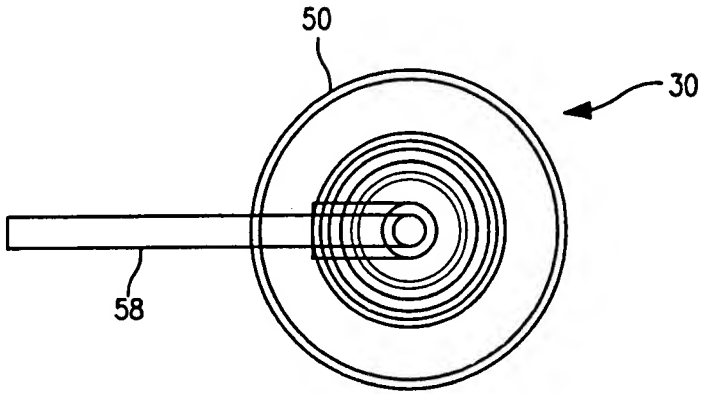


FIG. 11C

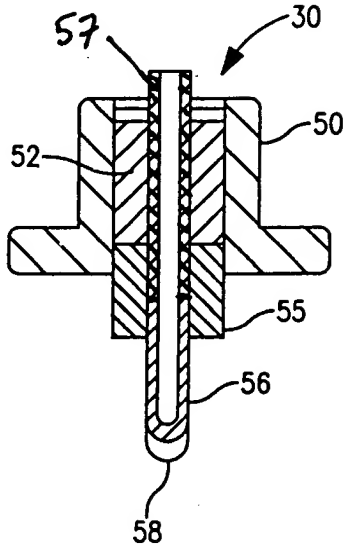


FIG. 11B

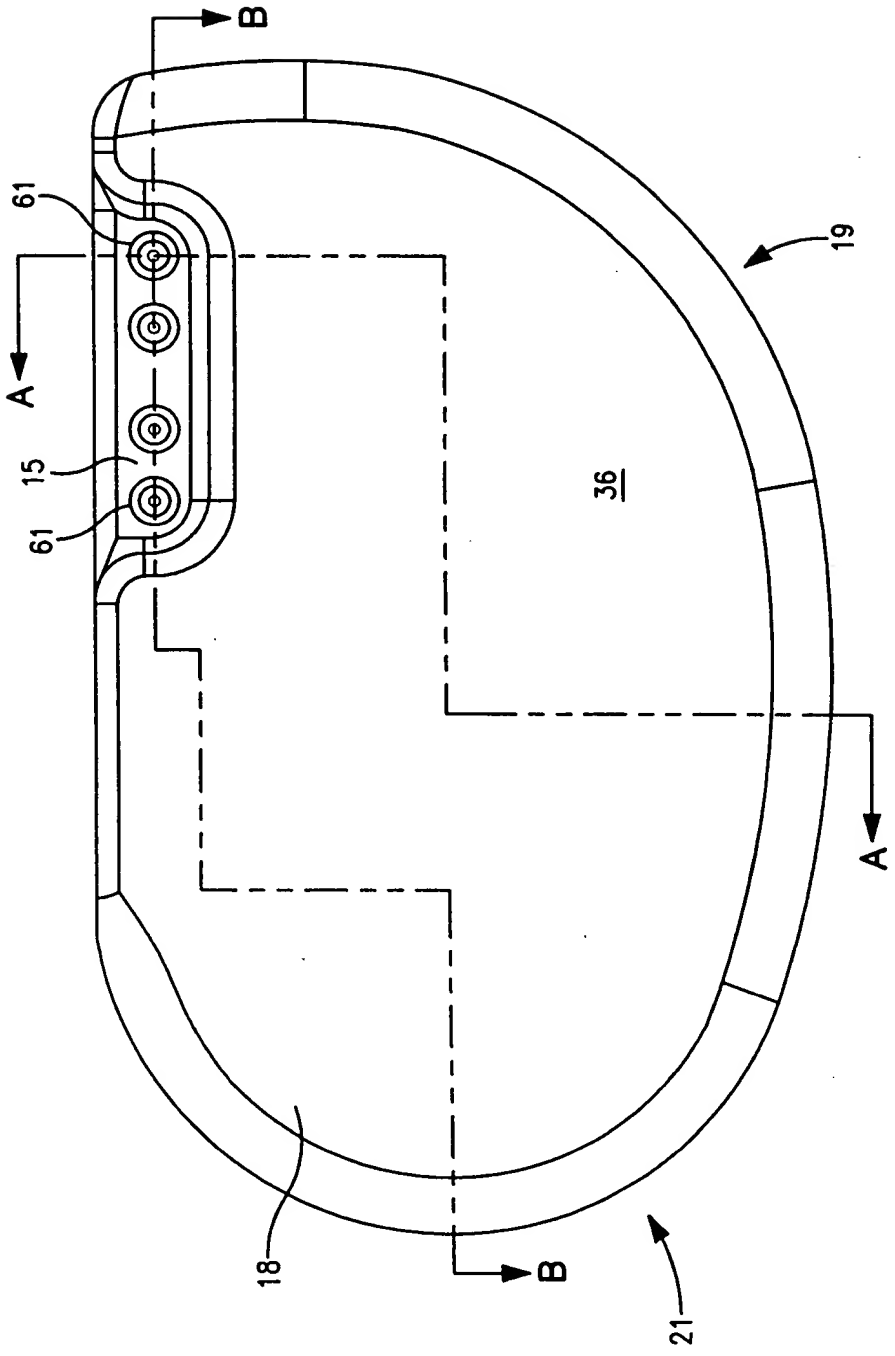


FIG. 12A

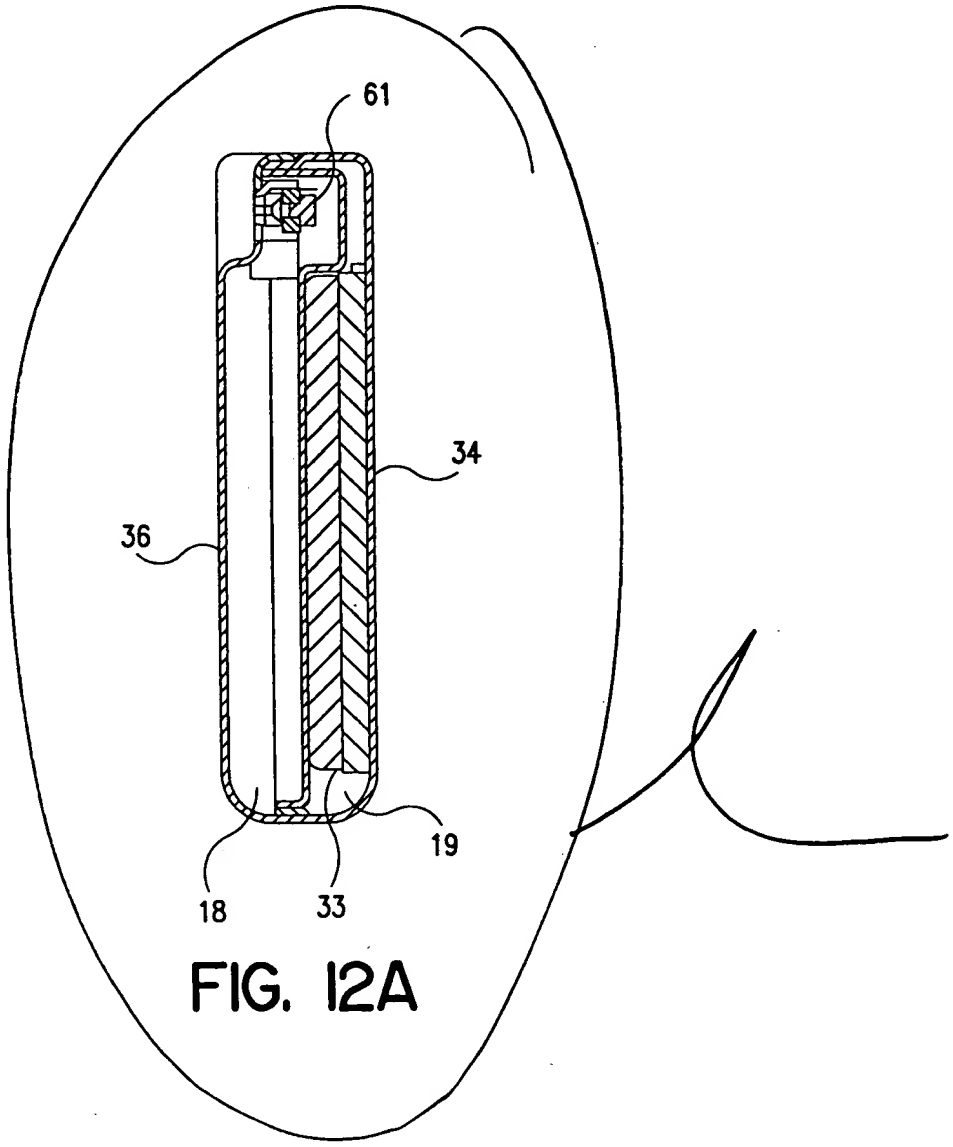


FIG. 12A